ORIGINAL ARTICLE e-ISSN: 2349-0659 p-ISSN; 2350-0964

Efficacy and Tolerability of Nixoderm Cream in the Management of Atopic Dermatitis: An Open-Label, Comparator-Controlled Clinical Study

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Abstract

Background: Topical formulations combining salicylic acid, benzoic acid, and precipitated sulfur have been reported to support the management of atopic dermatitis (AD) by aiding skin exfoliation, reducing microbial load, and easing inflammation. **Aims:** The aim of the study was to evaluate the efficacy and tolerability of Nixoderm Cream, applied twice daily, in subjects with AD, compared with a control arm. **Materials and Methods:** An open-label, parallel-group study was conducted at a single Centre following Ethics Committee approval. Forty two subjects diagnosed with AD per Hanifin–Rajka criteria were enrolled (Group A: Nixoderm Cream, *n* = 21; Group B: Control, *n* = 21) and assessed at day 0, 7, 15, and 30 using the Eczema area and severity index (EASI) and AD severity index (ADSI), alongside a structured patient-feedback questionnaire. **Results:** Group A showed statistically significant reductions in EASI and ADSI scores from baseline to day 30 in both full analysis set and per-protocol set analyses, while Group B showed slight improvement in EASI and ADSI. Between-group differences were statistically significant. No adverse events were reported in either arm. Patient-reported improvement in Group A rose to 88% by day 30. **Conclusion:** Nixoderm Cream demonstrated significant and well-tolerated improvement in AD severity over 30 days relative to control, supporting its potential role as a topical therapy for mild-to-moderate AD.

Keywords: Atopic dermatitis severity index, Atopic dermatitis, Eczema area and severity index, Nixoderm cream, Open-label study, Topical therapy

Asian Pac. J. Health Sci., (2026); DOI: 10.21276/apjhs.2026.13.4.01

Introduction

Atopic dermatitis (AD) is a common chronic, relapsing, and pruritic inflammatory skin disorder characterised by epidermal barrier dysfunction, immune dysregulation, and recurrent eczematous lesions.[1,2] It affects individuals across all age groups, with a particularly high prevalence in childhood. The global burden of AD has increased substantially over recent decades, with considerable impact on quality of life, sleep, work productivity, and psychosocial well-being.[2,3] The clinical manifestations vary with age and disease chronicity, ranging from erythematous and exudative lesions in infants to xerosis, excoriation, lichenification, and chronic eczematous plaques in older children and adults.[1,2] A personal or family history of atopic diseases, including asthma and allergic rhinitis, is frequently associated with AD.[1]

The management of AD aims to restore epidermal barrier function, control inflammation and pruritus, prevent exacerbations, and minimise treatment-related adverse effects. Regular use of emollients and avoidance of aggravating factors constitute the foundation of treatment, while topical corticosteroids remain the mainstay for controlling acute and chronic inflammatory flares.[2,4] However, concerns regarding cutaneous adverse effects, particularly with inappropriate or prolonged use, may limit their acceptability and adherence. Topical calcineurin inhibitors provide a steroid-sparing alternative, particularly for sensitive sites and long-term management, although transient burning or irritation may occur following application.[4,5] These therapeutic considerations highlight the continued need for effective, well-tolerated topical preparations that can complement conventional AD management.

Preparations containing keratolytic, antimicrobial, and anti-inflammatory ingredients have historically been used in the management of eczematous and hyperkeratotic skin disorders. Salicylic acid possesses keratolytic properties and may facilitate the removal of hyperkeratotic scales, whereas sulfur has keratolytic and antimicrobial activity. Benzoic acid is also recognised for its antimicrobial and antifungal properties.[6,7] The combination of these ingredients may therefore provide complementary effects in inflammatory and eczematous skin conditions. However, clinical evidence evaluating such combinations specifically in AD remains limited, warranting systematic assessment using objective disease-severity measures together with patient-reported outcomes.[9,10]

The present study was therefore undertaken to evaluate the efficacy and tolerability of Nixoderm Cream in subjects with AD, compared with a control formulation. Treatment response was assessed using a validated clinical severity measure along with a structured patient-feedback questionnaire to capture perceived improvement in symptoms, formulation effectiveness, and tolerability.

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How to cite this article: Hosthota A, Sridhar S, Sridhar S, Jayanthi CR, Singh K, Pujitha T, Chandran NS. Efficacy and Tolerability of Nixoderm Cream in the Management of Atopic Dermatitis: An Open-Label, Comparator-Controlled Clinical Study. Asian Pac. J. Health Sci., 2026;13(4):1-4.

Source of support: Nil.

Conflicts of interest: None.

Received: 01/07/2026 **Revised:** 17/07/2026 **Accepted:** 21/07/2026

Materials and Methods

Study Design

This was a prospective, open-label, parallel-group, comparator-controlled clinical study conducted at a single Centre – The Oxford Medical College, Hospital and Research Centre, Bengaluru was approved by the Institutional Ethics Committee before commencement, and written informed consent was obtained from all participants before enrolment.

Study Population

A total of 54 subjects were screened, of whom 42 met the inclusion/exclusion criteria and were enrolled (12 screen failures). Subjects were allocated to two parallel groups of 21 each: Group A received Nixoderm Cream, and Group B served as the control. Two subjects (Subject 19 and Subject 33) discontinued during Visit 2 (day 7); the full analysis set (FAS) comprised all 42 enrolled subjects, and the per-protocol set (PPS) excluded the two discontinued subjects and any other protocol deviators.

Eligibility Criteria

Inclusion criteria

Subjects of either sex, aged above 18 years, diagnosed with AD per Hanifin and Rajka clinical criteria[2] (≥3 of 4 major and ≥3 of 23 minor features), willing to provide informed consent, willing to complete study assessments and questionnaires, and willing to avoid other skin-care products for AD for at least 1 week before and throughout the study.

Exclusion criteria

Pregnancy or breastfeeding; other inflammatory or infective skin conditions; history of hypersensitivity to skin-care products; history of mild-to-severe anaphylaxis; pre-existing severe systemic disease requiring long-term medication; history of cancer, including solid tumors, hematologic malignancies, and carcinoma *in situ*; and participation in another clinical trial of an approved or investigational product within the preceding month.

Investigational Product and Dosing

Group A received Nixoderm Cream, applied twice daily to the affected areas of AD. Group B received the designated control regimen. Investigational products were dispensed at the baseline visit, and unused product was returned at the final visit.

Study Assessments

Subjects were assessed at Visit 1 (screening/day 0), Visit 2 (day 7, telephonic), Visit 3 (day 15), and Visit 4 (day 30). At baseline, demographic data, family history, and disease duration were recorded, and a comprehensive dermatological examination was performed. AD severity was assessed using the Eczema area and severity index (EASI),[3] which evaluates lesion morphology (erythema, papules, excoriation, lichenification) and affected body-surface area, and the AD severity index (ADSI). Standardized clinical photographs were taken at each visit. Safety assessments – medical and medication history, treatment history, physical examination, and assessment of comorbid conditions – were completed at baseline for all participants. Patient-reported outcomes were captured via a structured Product Efficacy Questionnaire and patient global impression of benefit–risk assessment at days 7, 15, and 30, covering perceived safety, noticeable symptom change, perceived benefit, and overall effectiveness. Adverse events were monitored and documented throughout the study.

Statistical Analysis

A statistical analysis plan was adopted as applicable, and descriptive statistical analysis was performed. For normally distributed data, parametric tests were applied; continuous measurements are presented as mean ± standard deviation, and categorical measurements as proportions. Subject feedback questionnaires were analyzed by frequency procedure and are presented as percentages. Both FAS and PPS analyses were performed for the efficacy endpoints.

Results

Subject Disposition

Of 54 subjects screened, 42 were enrolled (21 per group). Two subjects discontinued during Visit 2 (day 7). The FAS comprised 42 subjects; the PPS excluded the two discontinued subjects and any other protocol deviators.

Baseline Characteristics

Demographic characteristics assessed at Visit 1 were comparable between Group A and Group B in terms of height, weight, and BMI, with no statistically significant between-group differences. Vital signs (temperature, heart rate, pulse rate, respiratory rate, systolic and diastolic blood pressure) were within normal limits in both groups at baseline. No significant medical history or active comorbid conditions were observed, physical examination findings were within normal limits for all subjects, and no concomitant medications were reported during the study.

Efficacy Outcomes – EASI

In the FAS ($n = 42$), baseline EASI scores were comparable between groups. By day 30, Group A showed a significant reduction in EASI score compared with Group B ($P = 0.0005$); the within-group change from baseline was significant in Group A but not Group B, and the between-group change from baseline to day 30 was also significant ($P = 0.0004$), favoring Nixoderm Cream.

At baseline, the mean EASI scores were broadly comparable between Group A (5.10 ± 0.55) and Group B (4.92 ± 0.48), with no statistically significant difference ($P = 0.315$). Group A demonstrated a progressive reduction in EASI score from baseline to day 15 (4.62 ± 0.31) and day 30 (4.48 ± 0.36), indicating improvement in disease severity. Group B showed a smaller reduction on day 15 (4.86 ± 0.41), followed by an increase at day 30 (5.01 ± 0.40). Although Group A showed a more favorable numerical trend by day 30, the between-group difference was not statistically significant ($P = 0.373$) (Table 1).

Table 1: EASI scores – per-protocol set analysis

Time point	*Group A (nixoderm cream)*	*Group B (control)*	*P-value*
Baseline (day 0)	5.10±0.55	4.92±0.48	0.315
Day 15	4.62±0.31	4.86±0.41	0.359
Day 30	4.48±0.36	5.01±0.40	0.373

EASI: Eczema area and severity index

Table 2: ADSI scores – full analysis set (FAS) and per-protocol set (PPS)

Time point	*Group A – FAS*	*Group B – FAS*	*Group A – PPS*	*Group B – PPS*
Baseline (day 0)	11.12±1.50	10.68±1.24	11.12±1.50	10.69±1.25
Day 15	10.14±1.08	11.35±1.12	—	—
Day 30	9.28±1.09	12.14±1.29	9.28±1.09	12.34±1.12

ADSI: Atopic dermatitis severity index

Table 3: Perceived noticeable improvement in AD symptoms

Response	*Day 7 (%)*	*Day 15 (%)*	*Day 30 (%)*
Group A – yes (improved)	32	57	88
Group B (improved)	09	18	31

AD: Atopic dermatitis

Efficacy Outcomes – ADSI

Both groups had comparable baseline ADSI scores, with no statistically significant difference between the groups. By day 15, Group A showed an improvement in symptoms, as reflected by a reduction in the ADSI score from 11.12 ± 1.50 to 10.14 ± 1.08, whereas Group B showed an increase from 10.68 ± 1.24 to 11.35 ± 1.12. This trend continued through day 30, with the ADSI score decreasing further to 9.28 ± 1.09 in Group A and increasing to 12.14 ± 1.29 in Group B in the FAS. In the PPS, the day 30 scores were 9.28 ± 1.09 in Group A and 12.34 ± 1.12 in Group B. The between-group difference at day 30 was statistically significant ($P < 0.0001$ in both FAS and PPS). The overall direction of change remained favorable to Group A, indicating greater improvement in ADSI symptoms compared with Group B Table 2.

Patient-reported Outcomes

The proportion of participants reporting noticeable improvement in AD symptoms increased progressively over the 30-day observation period in both groups. In Group A, perceived improvement increased from 32% on day 7 to 57% on day 15 and 88% on day 30, indicating a consistent improvement over time. In Group B, improvement was reported by 9%, 18%, and 31% of participants on days 7, 15, and 30, respectively. Overall, Group A showed a higher and more sustained proportion of participants reporting noticeable symptom improvement compared with Group B throughout the observation period, with the difference being most pronounced by day 30.

Safety Outcomes

No adverse events or safety concerns were noted throughout the trial duration in either group.

Discussion

In this open-label, comparator-controlled study, Nixoderm Cream produced statistically significant and clinically consistent improvements in both EASI and ADSI scores over 30 days, with between-group differences favoring the active treatment arm across both FAS and PPS analyses. In contrast, the control arm showed a slight increase in EASI and ADSI over the same period, suggesting that the observed benefit in Group A reflects a genuine treatment effect rather than the natural course of the condition over the study period.

These clinician-assessed findings were corroborated by patient-reported outcomes: An increasing proportion of Group A participants reported noticeable improvement and perceived benefit over time, reaching 88% reporting improvement, while Group B participant rated their regimen as ineffective. Notably, no adverse events were reported in either arm, and all participants in both groups consistently rated their assigned product as safe, indicating that any efficacy difference was not achieved at the cost of tolerability Table 3.

These results are broadly consistent with the wider literature on topical anti-inflammatory therapy in AD, in which active topical agents have been shown to outperform comparator regimens on validated severity indices over similar treatment durations, while local tolerability profiles remain favorable.[4,9,10] As with other short-duration AD trials, a limitation of the present study is its 30-day follow-up period, which does not address durability of response or long-term safety; larger, multicenter, longer-duration studies would help confirm these findings and characterize the durability of benefit.

Conclusion

Nixoderm Cream demonstrated consistent and statistically significant improvement in AD severity over a 30-day period, evidenced by reductions in both EASI and ADSI scores and by increasingly favorable patient-reported outcomes, with no adverse events reported. The control group showed no comparable improvement over the same period. These findings support the efficacy and tolerability of Nixoderm Cream as a topical therapy for mild-to-moderate AD, warranting further evaluation in larger, longer-duration, multicenter trials.

Ethical Approval

The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and was approved by the Institutional Ethics Committee of The Oxford Medical College Hospital and Research Centre, Bengaluru.

Author Contributions

Dr. Abhineetha Hosthota: Conceptualization, study design, patient recruitment, clinical assessment, data interpretation, manuscript

preparation, critical revision, and final approval of the manuscript. Co-authors: Data collection, patient follow-up, data analysis, manuscript review, and final approval of the manuscript.

Data Availability Statement

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Acknowledgment

The authors acknowledge Ross Life science USA Inc for providing support for this study.

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